ARTICLE 61-06

HOME HEALTH CARE PHARMACY SERVICES

CHAPTER 61-06-01
HOME HEALTH CARE PHARMACY SERVICES

61-06-01-01. Definitions. For the purpose of this chapter, the following definitions apply:

1. **Pharmacy providing home health care pharmacy services.** A pharmacy providing home health care pharmacy services is a licensed pharmacy that routinely prepares and dispenses compounded, sterile parenteral products to outpatients.

2. **Outpatient.** An outpatient is defined as a patient in the home environment or an institutionalized patient that is receiving compounded sterile parenteral products from a pharmacy outside the institution.

3. **Compounded, sterile parenteral products.** Compounded, sterile parenteral products are defined as those parenteral drug products that require manipulation by the pharmacist and which must be sterile, stable, and effective when dispensed for patient use.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-06-01-02. Registration. All pharmacies providing home health care pharmacy services shall have a current pharmacy permit as provided by North Dakota law and rules of the board. They shall comply with all pharmacy laws and rules as well as the following special rules. The requirements of this chapter are in

addition to, and not in substitution for, other applicable laws of North Dakota and rules of the board.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-06-01-03. Personnel.

1. **Pharmacist-in-charge.** In addition to the pharmacist-in-charge requirements of section 61-02-01-10, that section of the pharmacy providing home health care pharmacy services must be managed by a pharmacist licensed to practice pharmacy in the state and who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile parenteral products, including the principles of aseptic technique and quality assurance. This knowledge is usually obtained through residency training programs, continuing education programs, or experience in an intravenous admixture facility. The pharmacist-in-charge is responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals and is also responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs. The pharmacist-in-charge may be assisted by additional pharmacists adequately trained in this area of practice.

2. **Supportive personnel.** The pharmacist managing the section of the pharmacy providing home health care pharmacy services may be assisted by supportive personnel. These personnel must have specialized training in this field, and shall work under the immediate supervision of a licensed pharmacist. The training provided to these personnel must be described in writing in a training manual. The duties and responsibilities of these personnel must be consistent with their training and experience.

3. **Secretarial support.** Secretarial support must be provided as required to assist with recordkeeping and other administrative duties.

4. **Staffing.** A pharmacist must be accessible at all times to respond to patients' and other health professionals' questions and needs.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-06-01-04. Physical requirements. The physical requirements are as follows:

1. **Space.** The pharmacy providing home health care pharmacy services shall have a designated area for preparing compounded, sterile parenteral products. This area must be physically separate from other areas and should be designed to avoid unnecessary traffic and airflow disturbances. It must be used only for the preparation of these specialty products. It must be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

2. **Equipment.**

   a. Laminar airflow hood.

   b. Infusion pumps, if appropriate.

   c. Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding.

   d. Facility for light/dark field examination.

   e. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents.

   f. A class II vertical flow biological safety cabinet, if chemotherapy agents are routinely prepared.

   g. Refrigerator/freezer.

3. **Supplies.**

   a. Disposable needles, syringes, and other supplies needed for aseptic admixture.

   b. Disinfectant cleaning solutions.

   c. Handwashing agent with bactericidal action.

   d. Disposable, lint-free paper towels.

   e. Appropriate filters and filtration equipment.

   f. Disposable masks and sterile, disposable gloves.

   g. Gowns, if chemotherapy agents are routinely prepared.

h. An oncology drug spill kit, if chemotherapy agents are routinely prepared.

4. **References.** In addition to references required in a retail pharmacy, current edition of an established reference on intravenous stability and incompatibility, such as, Handbook on Injectable Drugs, or King's Guide to Parenteral Admixtures.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14)

61-06-01-05. Drug distribution and control.

1. **General.** A drug distribution system is the entirety of that mechanism by which a physician's prescription is executed, from the time the drug is ordered and received in the primary, to the time the prescribed drug is dispensed to the patient.

2. **Purchasing.** All drugs and pharmaceutical products purchased and dispensed by a pharmacy providing home health care pharmacy services must meet national standards of quality (USP-NF standards) and must be clearly and accurately labeled by the manufacturer or distributor as to contents.

3. **Procedure manual.** A policy and procedure manual must be prepared and maintained at each pharmacy providing home health care pharmacy services and be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The manual must be reviewed and revised on an annual basis. A copy must be provided the board of pharmacy when applying for a permit or engaging in this specialized area of practice.

4. **Prescription.** The pharmacist or pharmacy intern acting under the immediate supervision of a pharmacist must receive a written or verbal prescription from a physician before dispensing any compounded, sterile parenteral product. Prescriptions must be filed as required by law or rules of the board.

5. **Profile.** A pharmacy generated profile must be maintained for each patient as required by North Dakota Century Code section 43-15-31.1, and must also include:

   a. Age.

   b. Weight.

   c. Sex.

d. Patient directions.

e. Other drugs patient is receiving.

f. Drug sensitivities and allergies to drugs and foods.

g. Primary diagnosis.

h. Documentation of patient training and continued competency.

i. Documentation of patient visits.

6. **Labeling.** Each compounded, sterile parenteral product dispensed to outpatients must be labeled with a permanent label with the following information:

a. Name, address, and telephone number of the pharmacy providing home health care pharmacy services.

b. Date and identifying prescription number.

c. Patient's full name.

d. Name of each drug, strength, and amount.

e. Directions for use to the patient, including infusion rate.

f. Physician's full name.

g. Required precautionary information.

h. Date and time of compounding.

i. Expiration date and time.

j. Identity of pharmacist compounding and dispensing.

7. **Records and reports.** The pharmacist managing the section of the pharmacy providing home health care pharmacy services shall maintain access to and submit, as appropriate, such records and reports as are required to ensure patient's health, safety, and welfare. Such records must be readily available, maintained for five years, and subject to inspections by the board of pharmacy or its agents. These must include, as a minimum, the following:

a. Policy and procedures manual.

b. Training manuals.

c. Policies and procedures for cytotoxic waste, if applicable.

d. Such other records and reports as may be required by law and rules of the board of pharmacy.

8. **Delivery service.** The pharmacist managing the section of the pharmacy providing home health care pharmacy services is responsible for the environment control of all products shipped. Therefore, any compounded, sterile parenteral product that is frozen, or requires refrigeration, must be shipped or delivered to a patient in appropriate coolers and stored appropriately in the patient's home.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-31, 43-15-31.1

61-06-01-06. Cytotoxic agents. The following additional requirements are necessary for those pharmacies providing home health care pharmacy services that routinely prepare chemotherapy agents to ensure the protection of the personnel involved:

1. All chemotherapy agents should be compounded in a vertical flow, class II, biological safety cabinet. If possible, other products should not be compounded in this cabinet.

2. Protective apparel must be worn by personnel compounding chemotherapy drugs. This includes disposable masks, gloves, and gowns with tight cuffs.

3. Proper aseptic and safety techniques must be used by personnel compounding chemotherapy agents.

4. Appropriate disposal procedures for cytotoxic waste must be developed that comply with applicable state and federal regulations.

5. Written procedures for handling both major and minor spills of cytotoxic agents must be developed.

6. Prepared doses of chemotherapy must be dispensed and shipped in a manner to minimize the risk of accidental rupture of the primary container.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-06-01-07. Patient care guidelines.

1. **Primary provider.** There must be a designated physician primarily responsible for the patient's medical care. There must be a clear understanding between the physician, the patient, and the pharmacist of the responsibilities of each in the areas of the delivery of care, the monitoring of the patient, and the reimbursement for services. This must be documented in the patient's profile.

2. **Patient training.** The patient, the patient's physician, or the patient's pharmacist shall demonstrate or document the patient's training and competency in managing this type of therapy in the home environment prior to any drugs, supplies, or equipment being dispensed. A pharmacist must be involved in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The pharmacist shall reassess and document on the profile the patient's competency in the necessary areas at least every six months.

3. **Pharmacist-patient relationship.** It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. The patient should be visited by the pharmacist at least monthly; telephone contact will not suffice. This must be documented in the patient's profile.

4. **Patient monitoring.** The pharmacist should have access to clinical and laboratory data concerning each patient and should monitor each patient's response to the patient's drug therapy. Any unexpected or untoward response should be reported to the prescribing physician.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-06-01-08. Quality control. There must a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. The end product must be examined on a sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications.

1. **Hood certification.** All laminar flow hoods must be certified by federal standard 209B for operational efficiency at least every twelve months. Appropriate records must be maintained.

2. **Prefilters.** Prefilters for the clean air source must be replaced on a regular basis and these activities documented.

3. **Bulk compounding.** If bulk compounding of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine. This process must include testing for sterility and pyrogens.

4. **Expiration dates.** If the product is assigned a lengthy expiration date (anything exceeding ten days), there must be in-house data or data in the literature to assure the sterility and stability of the product at the time it is used by the patient.

5. **Quality control audits.** There must be documentation of quality assurance audits at regular, planned intervals.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)